

01/05/04

**MEMORANDUM IN SUPPORT OF MOTION FOR PROTECTIVE ORDER OF
BOEHRINGER INGELHEIM CORPORATION, BEN VENUE LABORATORIES, INC.,
AND BEDFORD LABORATORIES**

Facts

Defendants Boehringer Ingelheim Corp., Ben Venue Laboratories, and Bedford Laboratories are three entities referred to by Plaintiffs as the “Boehringer Group.” *See* AMCC ¶¶ 64-66. Plaintiffs have alleged, *inter alia*, that Defendants, along with several other pharmaceutical companies, manipulated Average Wholesale Prices (“AWPs”) of both multi-source and brand-named drugs in a scheme to defraud drug purchasers. *See, e.g.*, AMCC ¶ 313. Defendants were served with Plaintiffs’ Master Consolidated Class Action Complaint (“MCC”) out of this Court (sitting as the Multidistrict Litigation consolidating court) on or around September 9, 2002. After a round of motions to dismiss/motions for a more definite statement, this Court granted Plaintiffs leave to amend their Complaint. Defendants were served with the AMCC on or around June 12, 2003; Defendants filed both a joint motion² and individual motions to dismiss on August 1, 2003 and reply memorandum on September 30, 2003.

On November 21, 2003, this Court heard oral argument on the motions to dismiss the AMCC. At the conclusion of that hearing, the Court instructed that discovery would go forward on non-multisource drugs which had been alleged with “specificity” in the AMCC. *See* Ex. B (Nov. 21, 2003 Oral Argument, Uncorrected Tr. 117-20). This Court has not yet ruled on Defendants’ motions to dismiss the AMCC.

On December 3, 2003, Plaintiffs served Defendants with a Request for Production of Documents and Interrogatories. *See* Ex. C. Plaintiffs sought discovery from Defendants only on the brand-named drug, Viramune – that drug being the only brand-named drug allegedly

² With other pharmaceutical industry defendants not represented by present counsel.

associated with Defendants that is subject to discovery per this Court's November 21, 2003 Order. *See* Ex. C at Req. Ex. A, page 6.

Defendants sent Plaintiffs a letter on or about December 4, 2003, which explained their grounds for rejecting Plaintiffs' request for discovery, and which invited Plaintiffs to contact Defendants "[i]f you have a different view, or have any questions about our position on discovery." Ex. A. Plaintiffs did not respond to this invitation to confer within the seven days required by Local Rule 37.1, and remain unresponsive. Defendants now seek a Protective Order from discovery.

Argument

Federal Rule of Civil Procedure 26 provides

(c) **Protective Orders.** Upon motion by a party or by the person from whom discovery is sought, accompanied by a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action, and for good cause shown, the court in which the action is pending or alternatively, on matters relating to a deposition, the court in the district where the deposition is to be taken may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) that the disclosure or discovery not be had

.....
Plaintiffs seek discovery from Defendants only on Viramune. Discovery should not be had at least until such time as this Court rules on Defendants' motions to dismiss for three reasons: (1) Viramune is not identified in Appendix A of Plaintiff's AMCC as an Average Wholesale Price Inflated Drug ("AWPID") subject to the claims alleged the AMCC; (2) Viramune is not manufactured or distributed by any of the entities identified as members of the "Boehringer Group" in paragraphs 64-66 of the AMCC; and (3) Plaintiffs have not alleged a fraudulent AWP for Viramune anywhere in the AMCC as required by this Court's May 13, 2003 Order.

Viramune is not the subject of any claims in the AMCC

The scope of discovery is generally limited to that which is “relevant to the claim or defense of any party.” Fed. R. Civ. P. 26(b)(1). The Committee Notes clearly reflect that the Court has authority “to confine discovery to the claims and defenses asserted in the *pleadings*” and that Plaintiffs “have no entitlement to discovery to develop new claims . . . that are *not already identified in the pleadings*.” *Id.* at Advisory Comm. Note 2000 Amend., GAP Report, Subdivision (b)(1) (emphasis added). Furthermore, per this Court’s instructions at the hearing, discovery is limited to those non-multisource drugs that have been alleged with “specificity.” Ex. B (Nov. 21, 2003 Oral Argument Uncorrected Tr. at 117-18). Limiting discovery to those allegations that conform with this Court’s orders is well within the discretion of this Court. *See Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 244 F.3d 189, 192 (1st Cir. 2001).

Plaintiffs have not identified Viramune as a drug subject to any claim in this suit. Paragraph 11 of the AMCC states “plaintiffs have prepared a list of each of the *specific drugs* that are the *subject of the claims* herein. *This list is attached as Exhibit A to the Complaint.*”³ The drugs identified in *Exhibit A* will be referred to herein as the AWP Inflated Drugs (“AWPID” or “AWPIDs”).” Plaintiffs reiterate in their Request for Production of Documents that “AWPID” means “any of the drugs identified in Appendix A.” *See* Ex. C part I, ¶ 10; *cf.*, *e.g.*, *id.* part V, No. 3-10.

Appendix A of the AMCC does not list Viramune as an AWPID. Therefore, by the Plaintiffs’ own enumeration of the scope of drugs at issue, Viramune is not the subject of this litigation. Defendants should be protected from Plaintiffs’ attempt to compel discovery on drugs that – by Plaintiffs’ own Complaint – are not in dispute. *See* Fed. R. Civ. P. 26(b)(1).

³ Plaintiffs appear to use “Exhibit A” and “Appendix A” interchangeably to refer to Appendix A.

Furthermore, protecting Defendants from discovery will further this Court's goals of conducting orderly discovery and keeping this case to manageable proportions. Whether Viramune is a brand-named drug properly alleged in the AMCC is an issue still pending in Defendants' motion to dismiss. "Requiring extensive investigation would defeat the purpose of [the] motion," if discovery is to proceed against Defendants on this very drug. *Transunion Corp. v. PepsiCo, Inc.*, 811 F.2d 127, 130 (2d Cir. 1987) (upholding protective order pending motion to dismiss on grounds of forum nonconveniens); *see also In re Showa Denko K.K. L-Tryptophan Prod. Liab. Litig.*, 953 F.2d 162, 165 (4th Cir. 1992) (trial court has broad discretion to limit and manage discovery in multidistrict litigation "to minimize expense to all litigants and to provide judicial efficiency").

Viramune is not manufactured or distributed by any of the named Defendants

Discovery against Defendants should also be denied because Viramune is not manufactured or distributed by any of the named Defendants, as Defendants have previously asserted in their individual "Motion to Dismiss the Amended Master Consolidated Class Action Complaint" filed August 1, 2003. *See* Def. Boehringer Ingelheim Corp., Ben Venue Labs, Bedford Labs Mot. to Dismiss AMCC at 2.

Plaintiffs have identified Defendants Boehringer Ingelheim Corporation, Ben Venue Laboratories, Inc., and Bedford Laboratories as members of the "Boehringer Group." And yet, none of these identified parties manufactures or distributes Viramune as alleged by the Plaintiff, and as a cursory examination of industry literature, such as the Physician's Desk Reference, would reveal. *See* PHYSICIANS' DESK REFERENCE ("PDR") 991, 1028-29 (Thompson 58th ed.

2004); PDR 1023, 1055, 1059 (57th ed. 2003); PDR 1026, 1060 (56th ed. 2002); PDR 2823, 2842 (55th ed. 2001); *cf.* 21 C.F.R. § 201.100(d)(1) (specifying information for drug labeling).

As Viramune is not a drug belonging to any of the Defendants identified in Plaintiffs' own Complaint, Plaintiffs should not be able to pursue discovery against Defendants.

Defendants do not allege any AWP for Viramune as required by this Court's May 13 Order

Finally, Defendants deserve protection from discovery because Plaintiffs have not alleged Viramune with the specificity required to make it properly part of this lawsuit. This Court's Memorandum and Order of May 13, 2003 held that pursuant to Fed. R. Civ. P. 8 & 9 any amendment to the Master Consolidated Complaint must "clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." May 13 Order at 44-45.

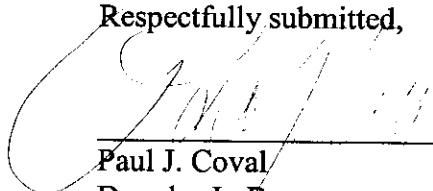
Despite this clear instruction, Plaintiffs have failed to conform their AMCC to this Court's Order. Although Plaintiffs have attempted to identify Viramune and a specific purchaser, Plaintiffs have not clearly identified an allegedly fraudulent AWP anywhere in Appendix B or elsewhere in the AMCC as required by this Court's Order. *See* AMCC, App. B. *Compare* AMCC App. A *with* AMCC App. B.

Further, as stated above, whether any of Defendants' alleged products are properly in dispute in this case will be decided by the Court on a motion to dismiss. By this Court's own November 21, 2003 Order, only those non-multisource drugs that are alleged with the requisite specificity are currently subject to discovery. Nothing in this Court's orders holds Plaintiffs to a lesser threshold of specificity for discovery than for the pleading itself. Because Viramune is a

drug where the specificity of pleading is plainly deficient, this Court should protect Defendants from discovery at least until such time as it rules on the dispositive motions. *See Transunion*, 811 F.2d at 130.

For the foregoing reasons Defendants' Motion for Protective Order should be granted.

Respectfully submitted,



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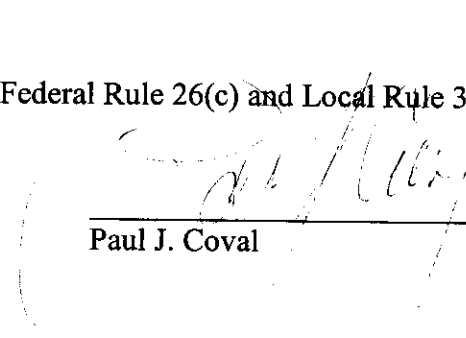
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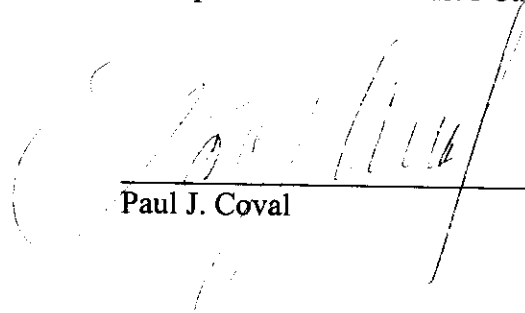
I hereby certify that the provisions of Federal Rule 26(c) and Local Rule 37.1 have been complied with.



Paul J. Coval

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document was served on all enrolled counsel via Verilaw on December 31, 2003 pursuant to this Court's Case Management Order 2.



Paul J. Coval